



106TH CONGRESS  
2D SESSION

# S. 2366

To amend the Public Health Service Act to revise and extend provisions relating to the Organ Procurement and Transplantation Network.

---

## IN THE SENATE OF THE UNITED STATES

APRIL 5, 2000

Mr. FRIST (for himself, Mr. JEFFORDS, Mr. GREGG, Mr. ENZI, Mr. HUTCHINSON, Ms. COLLINS, Mr. BROWNBACK, Mr. HAGEL, and Mr. SESSIONS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act to revise and extend provisions relating to the Organ Procurement and Transplantation Network.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Organ Procurement  
5 and Transplantation Network Amendments Act of 2000”.

6 **SEC. 2. ORGAN PROCUREMENT AND TRANSPLANTATION**  
7 **NETWORK.**

8 (a) IN GENERAL.—Section 372 of the Public Health  
9 Service Act (42 U.S.C. 274) is amended to read as follows:

1   **“SEC. 372. ORGAN PROCUREMENT AND TRANSPLANTATION**  
2                   **NETWORK.**

3           “(a) ESTABLISHMENT OF NETWORK.—

4                   “(1) IN GENERAL.—An Organ Procurement  
5           and Transplantation Network (in this section re-  
6           ferred to as the ‘Network’ or the ‘OPTN’) is estab-  
7           lished as a private network and shall operate under  
8           this section.

9                   “(2) REQUIREMENTS.—The Network shall—

10                           “(A) in accordance with criteria developed  
11                   under subsection (c)(1)(B), include as members  
12                   of the Network qualified organ procurement or-  
13                   ganizations (as described in section 371(b)),  
14                   transplant centers, and other entities that have  
15                   a demonstrated interest in the fields of organ  
16                   donation or transplantation (such members  
17                   shall be referred to in this section as ‘Network  
18                   participants’); and

19                           “(B) have a policy board (referred to in  
20                   this section as the ‘OPTN Board’) that meets  
21                   the requirements of subsection (b).

22           “(b) OPTN POLICY BOARD.—

23                   “(1) COMPOSITION.—The OPTN Board shall  
24           be composed of not more than 36 voting members  
25           to be elected under paragraph (2) and 5 nonvoting,  
26           ex officio members appointed under paragraph (3).

1           “(2) ELECTED MEMBERS.—

2                   “(A) IN GENERAL.—The voting members  
3 of the OPTN Board shall be elected by the  
4 members of the Network described in sub-  
5 section (a)(2)(A), from among the nominees  
6 submitted under subparagraph (B), through a  
7 fair and open process.

8                   “(B) NOMINATING COMMITTEE.—The  
9 nominating committee established under para-  
10 graph (5) shall, prior to each election of OPTN  
11 Board members under this paragraph, develop  
12 a list of nominees for such election. Such list  
13 shall reflect the diversity of Network members  
14 described in subsection (a)(2)(A), including fac-  
15 tors such as program type and size and geo-  
16 graphic location. Recommendations may be sub-  
17 mitted to the nominating committee by the Sec-  
18 retary, the members of the Network described  
19 in subsection (a)(2)(A), or the general public.

20                   “(C) QUALIFICATIONS.—The OPTN Board  
21 shall be composed of—

22                           “(i) transplant surgeons and trans-  
23                           plant physicians;

24                           “(ii) representatives of qualified organ  
25                           procurement organizations, transplant cen-

1           ters, voluntary health associations, or the  
2           general public, including patients awaiting  
3           a transplant or transplant recipients or in-  
4           dividuals who have donated an organ, or  
5           the family members of such patients, re-  
6           cipients or donors; and

7           “(iii) individuals distinguished in the  
8           fields of ethics, basic, clinical and health  
9           services research, biostatistics, health care  
10          policy, or health care economics or financ-  
11          ing.

12          “(D) REPRESENTATION REQUIREMENT.—  
13          The OPTN Board shall be structured to ensure  
14          that—

15               “(i) at least 50 but not more than 55  
16               percent of the members elected under this  
17               paragraph are transplant surgeons and  
18               transplant physicians; and

19               “(ii) at least 20 but not more than 25  
20               percent of the members elected under this  
21               paragraph are transplant candidates,  
22               transplant recipients, organ donors and  
23               family members of such individuals.

24          Nothing in this subparagraph shall be con-  
25          strued to preclude an individual voting member



1 of the OPTN Board from being a representa-  
2 tive described in each of clauses (i) and (iii) or  
3 (ii) and (iii) of subparagraph (C) so long as the  
4 limitation described in clause (i) of this sub-  
5 paragraph is complied with.

6 “(3) APPOINTED MEMBERS.—

7 “(A) IN GENERAL.—The Secretary shall  
8 appoint as ex officio, nonvoting members of the  
9 OPTN Board, 1 representative from each of the  
10 following:

11 “(i) The Health Resources and Serv-  
12 ices Administration.

13 “(ii) The National Institutes of  
14 Health.

15 “(iii) The Health Care Financing Ad-  
16 ministration.

17 “(iv) The Agency for Healthcare Re-  
18 search and Quality.

19 “(B) NETWORK ADMINISTRATOR.—The  
20 Network Administrator shall appoint an ex offi-  
21 cio nonvoting member of the OPTN Board.

22 “(4) TERMS OF ELECTED MEMBERS.—

23 “(A) IN GENERAL.—Except as provided  
24 for in this paragraph, members of the OPTN

1 Board elected under paragraph (2) shall serve  
2 for a term of 3 years and may be re-elected.

3 “(B) NEW MEMBERS.—To ensure the stag-  
4 gered rotation of  $\frac{1}{3}$  of the elected members of  
5 the OPTN Board each year, the initial mem-  
6 bers of the OPTN Board elected under para-  
7 graph (2) shall serve for terms of 1, 2, or 3  
8 years respectively as designated by the nomi-  
9 nating committee.

10 “(C) TRANSITION.—Consistent with sub-  
11 section (c)(3), the voting members of the  
12 OPTN Board who are serving on the date of  
13 enactment of the Organ Procurement and  
14 Transplantation Network Amendments Act of  
15 2000 may continue to serve until the expiration  
16 of their terms. Upon such termination, the  
17 nominating committee, in submitting nomina-  
18 tions to fill such vacancies, shall ensure the  
19 staggered rotation of  $\frac{1}{3}$  of the members elected  
20 under paragraph (2) every 3 years.

21 “(D) CONTRACT STATUS.—A change in the  
22 status of a contract under subsection (f), or a  
23 change in the contractor, shall not affect the  
24 terms of the members of the OPTN Board.

1           “(5) CHAIRPERSON AND COMMITTEES.—The  
2       OPTN Board shall have a chairperson, an executive  
3       committee, a nominating committee, a membership  
4       committee, and such other committees as the OPTN  
5       Board determines to be appropriate.

6       “(c) GENERAL FUNCTIONS OF THE OPTN BOARD.—

7           “(1) ESTABLISHMENT OF NETWORK POLICIES  
8       AND CRITERIA.—The OPTN Board shall—

9           “(A) after consultation with Network par-  
10       ticipants and the Network Administrator, estab-  
11       lish and carry out the policies and functions de-  
12       scribed in this section for the Network;

13          “(B) establish membership criteria for par-  
14       ticipating in the Network;

15          “(C) establish medical criteria for allo-  
16       cating organs and for listing and de-listing pa-  
17       tients on the national lists maintained under  
18       paragraph (2); and

19          “(D) establish performance criteria for  
20       transplant programs.

21       “(2) NATIONAL SYSTEM.—The OPTN Board  
22       shall maintain a national system to match organs  
23       and individuals who need organ transplants. The na-  
24       tional system shall—

1                   “(A) have 1 or more lists of individuals  
2                   who are in need of organ transplants; and

3                   “(B) be operated in accordance with Net-  
4                   work policies and criteria established under  
5                   paragraph (1).

6                   “(3) NO FIDUCIARY RESPONSIBILITY.—The  
7                   OPTN Board shall have no voting member who has  
8                   any fiduciary responsibility to the entity that holds  
9                   the contract provided for under this section.

10                  “(4) OPTN BOARD REQUIREMENTS.—The  
11                  OPTN Board shall cooperate with the Network Ad-  
12                  ministrators to ensure compliance with the require-  
13                  ments of this section including the contract entered  
14                  into under subsection (f).

15                  “(d) ORGAN TRANSPLANT POLICY.—The OPTN  
16                  Board shall establish organ transplant policies, including  
17                  organ allocation policies for potential organ recipients and  
18                  policies that affect patient outcomes. Such policies shall—

19                         “(1) be based on sound medical principles;

20                         “(2) be based on valid scientific data;

21                         “(3) be equitable;

22                         “(4) seek to achieve the best use of donated or-  
23                         gans;

24                         “(5) be designed to avoid wasting organs, to  
25                         avoid futile transplants and reduce the risk of re-



1 transplantation, to promote patient access to trans-  
2 plantation, and to promote the efficient management  
3 of organ placement;

4 “(6) be specific for each organ type or combina-  
5 tion of organ types;

6 “(7) be based on standardized medical criteria  
7 for listing and de-listing candidates from organ  
8 transplant waiting lists;

9 “(8) determine priority rankings (within cat-  
10 egories as appropriate) for candidates who are medi-  
11 cally suitable for transplantation, such rankings  
12 shall be based on standardized medical criteria and  
13 ordered according to medical urgency and medical  
14 appropriateness;

15 “(9) seek distribution of organs as appropriate  
16 based on paragraphs (1) through (8);

17 “(10) develop and apply appropriate perform-  
18 ance indicators, including patient-focused indicators,  
19 to assess transplant program performance and re-  
20 duce inter-transplant program variance to improve  
21 program performance; and

22 “(11) seek to reduce disparities in transplan-  
23 tation resulting from socioeconomic status, race, eth-  
24 nicity, or being medically underserved.

1       “(e) ENFORCEMENT OF ORGAN TRANSPLANT POL-  
2 ICY.—

3               “(1) IN GENERAL.—

4                       “(A) PROPOSED POLICY.—This paragraph  
5 shall apply to any proposed transplant policy  
6 that is developed by the OPTN Board that the  
7 Board or the Secretary determines should be  
8 enforced under this section or under section  
9 1138 of the Social Security Act.

10                      “(B) SUBMISSION OF POLICY.—Not later  
11 than 60 days prior to the implementation of a  
12 proposed policy described in subparagraph (A),  
13 the OPTN Board shall submit such proposed  
14 policy to the Secretary.

15                      “(C) PUBLICATION.—Upon receipt of a  
16 proposed policy under subparagraph (B), the  
17 Secretary shall publish the policy in the Federal  
18 Register for a 60-day public comment period.

19                      “(D) ACTION BY SECRETARY.—Not later  
20 than 90 days after receipt of a proposed policy  
21 under subparagraph (B), the Secretary shall  
22 consider public comments received under sub-  
23 paragraph (C) and shall—

1           “(i) notify the OPTN Board that the  
2 policy is consistent with this section and  
3 therefore enforceable; or

4           “(ii) notify the OPTN Board that the  
5 policy is inconsistent with this section and  
6 direct the Board to reconsider and revise  
7 the policy consistent with the recommenda-  
8 tions of the Secretary.

9           “(E) RECONSIDERATION.—

10           “(i) IN GENERAL.—Not later than 30  
11 days after receiving a notice from the Sec-  
12 retary under subparagraph (D)(ii), the  
13 OPTN Board shall reaffirm the proposed  
14 policy or revise and submit such revised  
15 policy to the Secretary.

16           “(ii) ACTION BY SECRETARY.—Not  
17 later than 30 days after receiving a revised  
18 policy under clause (i), the Secretary  
19 shall—

20           “(I) notify the OPTN Board that  
21 the revised policy is consistent with  
22 this section and therefore enforceable;  
23 or

24           “(II) notify the OPTN Board  
25 that the revised policy is inconsistent

1 with this section and submit the re-  
2 vised policy, with the comments and  
3 proposed revisions of the Secretary, to  
4 the Scientific Advisory Committee on  
5 Organ Transplantation (referred to in  
6 this subsection as the 'Committee') es-  
7 tablished under paragraph (2).

8 “(iii) ACTION BY COMMITTEE.—Not  
9 later than 30 days after the submission of  
10 a revised policy to the Committee under  
11 clause (ii), the Committee may, by a ma-  
12 jority vote, disapprove the comments or re-  
13 vision of the Secretary. If the Committee  
14 disapproves such comments or revisions,  
15 the revised policy shall not take effect until  
16 a majority of the Committee approves the  
17 policy or the revisions to such policy.

18 “(2) SCIENTIFIC ADVISORY COMMITTEE ON  
19 ORGAN TRANSPLANTATION.—

20 “(A) ESTABLISHMENT.—The Secretary  
21 shall establish an advisory committee to be  
22 known as the Scientific Advisory Committee on  
23 Organ Transplantation. Consistent with the re-  
24 quirements of sections 5 and 10 of the Federal  
25 Advisory Committee Act—



1           “(i) the deliberations of the Com-  
2           mittee shall not be inappropriately influ-  
3           enced by the Secretary or by any special  
4           interest and shall only be the result of the  
5           independent judgment of the Committee;  
6           and

7           “(ii) the meetings of the Committee  
8           shall be open to the public, advance notice  
9           of meetings shall be published in the Fed-  
10          eral Register, and records or minutes of  
11          meetings shall be made available to the  
12          public.

13          “(B) DUTIES.—The Committee shall make  
14          recommendations with respect to policy matters  
15          related to reviews conducted under paragraph  
16          (1)(E)(ii)(II).

17          “(C) MEMBERSHIP.—The Committee shall  
18          be composed of 15 members, of which—

19               “(i) five members shall be appointed  
20               by the Secretary from nominations sub-  
21               mitted by the OPTN Board under sub-  
22               paragraph (D);

23               “(ii) five members shall be appointed  
24               by the Secretary from nominations sub-

1           mitted by the Institute of Medicine under  
2           subparagraph (D); and

3           “(iii) five members shall be appointed  
4           by the Secretary.

5           “(D) NOMINATIONS.—The OPTN Board  
6           and the Institute of Medicine shall each nomi-  
7           nate, in an independent manner, 5 qualified in-  
8           dividuals to serve on the Committee.

9           “(E). QUALIFICATIONS.—In appointing in-  
10          dividuals to serve on the Committee under sub-  
11          paragraph (C), the Secretary shall ensure  
12          that—

13               “(i) nine members are transplant phy-  
14               sicians or transplant surgeons of whom—

15                       “(I) 3 shall be selected from the  
16                       nominations submitted by the OPTN  
17                       Board; and

18                       “(II) 3 shall be selected from the  
19                       nominations submitted by the Insti-  
20                       tute of Medicine; and

21               “(ii) the remaining members are indi-  
22               viduals who are—

23                       “(I) distinguished in the fields of  
24                       ethics, basic, clinical or health services

1 research, biostatistics, or health care  
2 policy, economics or financing; or

3 “(II) transplant candidates,  
4 transplant recipients, organ donors or  
5 family members of such individuals.

6 “(F) EXPERTS.—The Committee shall  
7 seek advice from appropriate experts, as need-  
8 ed, to evaluate the proposed policy and revisions  
9 under review.

10 “(G) CHAIRPERSON.—The members of the  
11 Committee shall elect a member to serve as the  
12 chairperson of the Committee.

13 “(H) TERMS.—Members of the Committee  
14 shall serve for a term of 5 years. Vacancies  
15 shall be filled in the same manner as the origi-  
16 nal appointment was made.

17 “(f) NETWORK ADMINISTRATION AND OPERATION.—  
18 The Secretary shall contract with a nonprofit private enti-  
19 ty (referred to in this section as the ‘Network Adminis-  
20 trator’) for the administration and operation of the Net-  
21 work. The Network Administrator shall administer and  
22 operate the OPTN Board in accordance with subsection  
23 (b). The Network Administrator shall, pursuant to the  
24 policies and criteria established by the OPTN Board—

1           “(1) maintain and operate a national system as  
2       established by the OPTN Board to match organs  
3       and individuals who need organ transplants;

4           “(2) operate in accordance with medical criteria  
5       established by the OPTN Board, and administer the  
6       national system established under subsection (c)(2);

7           “(3) maintain 1 or more lists of individuals who  
8       need organ transplants as provided for under sub-  
9       section (c)(2)(A);

10          “(4) maintain a 24-hour communication service  
11       to facilitate matching organs with individuals in-  
12       cluded on the list or lists;

13          “(5) assist organ procurement organizations in  
14       obtaining and distributing organs in accordance with  
15       the policies established by the OPTN Board;

16          “(6) adopt and use standards of quality for the  
17       acquisition and transportation of donated organs, in-  
18       cluding standards regarding the transmission of in-  
19       fectious diseases;

20          “(7) prepare and distribute, on a regionalized  
21       basis (and, to the extent practicable, among regions  
22       or on a national basis), samples of blood sera from  
23       individuals who are included on the list in order to  
24       facilitate matching the compatibility of such individ-  
25       uals with organ donors;



1           “(8) coordinate, as appropriate, the transpor-  
2       tation of organs from organ procurement organiza-  
3       tions to transplant centers;

4           “(9) provide information to physicians, health  
5       care professionals, and the general public regarding  
6       organ donation;

7           “(10) carry out studies and demonstration  
8       projects for the purpose of improving procedures for  
9       organ procurement and allocation; and

10          “(11) work actively with organ procurement or-  
11       ganizations, transplant centers, health care pro-  
12       viders, and the public to increase the supply of do-  
13       nated organs.

14       “(g) DATA COLLECTION, ANALYSIS AND DISTRIBUTION.—  
15

16          “(1) IN GENERAL.—The Network Adminis-  
17       trator shall analyze, maintain, verify, make available  
18       and publish timely data to the extent necessary to—

19               “(A) enable the OPTN Board to fulfill its  
20       responsibilities under this section;

21               “(B) assess the compliance of members of  
22       the Network with performance and other cri-  
23       teria developed pursuant to subsection (c)(1);

1 “(C) evaluate the quality of care provided  
2 to transplant candidates and patients generally  
3 and in an individual program;

4 “(D) provide data needed by the Scientific  
5 Registry maintained pursuant to section 373;

6 “(E) provide transplant candidates and pa-  
7 tients, physicians and others with information  
8 needed to evaluate or select a transplant pro-  
9 gram;

10 “(F) provide a member of the Network  
11 with data about the member, including results  
12 of analysis or other processing of data originally  
13 supplied by the member;

14 “(G) enable the OPTN Board, the Net-  
15 work Administrator and the Secretary to fulfill  
16 respective enforcement and oversight respon-  
17 sibilities under subsections (j) and (k); and

18 “(H) comply with the requirements under  
19 subsection (l).

20 “(2) TYPES OF DATA.—Data provided under  
21 paragraph (1) shall include—

22 “(A) data on transplant candidates, trans-  
23 plant recipients, organ donors, donated organs,  
24 and transplant programs; and

1                   “(B) as appropriate, data, graft- and pa-  
2                   tient-survival rates (actual and adjusted to re-  
3                   flect program-specific population disease sever-  
4                   ity), program specific data, and aggregate data.

5           “(h) CONTRACT.—The contract under subsection (f)  
6 shall—

7                   “(1) be awarded through a process of competi-  
8                   tive bidding as determined by the Secretary; and

9                   “(2) be awarded for a period of no longer than  
10           5 years.

11           “(i) NETWORK MEMBERSHIP AND PATIENT REG-  
12 ISTRATION FEE.—

13                   “(1) IN GENERAL.—The Network Adminis-  
14                   trator may assess a fee, to be collected by the Net-  
15                   work Administrator, for membership in the Network  
16                   (to be known as the ‘Network membership fee’), and  
17                   for the listing of each potential transplant recipient  
18                   on the national organ matching system maintained  
19                   by the Network Administrator (to be known as the  
20                   ‘patient registration fee’), in an amount determined  
21                   under paragraph (2).

22                   “(2) AMOUNT.—The amounts of the fees to be  
23                   assessed under paragraph (1) shall be calculated so  
24                   as to be—

25                   “(A) reasonable and customary; and

1           “(B) sufficient to cover the Network’s rea-  
2           sonable costs of operation in accordance with  
3           this section.

4           “(3) ANNUAL RECALCULATION.—

5           “(A) IN GENERAL.—The fees calculated  
6           under paragraph (2) shall be annually recal-  
7           culated, based on—

8           “(i) changes in the level or cost of  
9           contract tasks and other activities related  
10          to organ procurement and transplantation;  
11          and

12          “(ii) changes in expected revenues  
13          from contract funds, Network membership  
14          fees and patient registration fees available  
15          to the Network Administrator.

16          “(B) PROCEDURE.—

17          “(i) PROPOSAL.—The Network Ad-  
18          ministrator shall submit to the Secretary a  
19          written proposal for, and justification of, a  
20          recalculated fee under subparagraph (A).

21          “(ii) DETERMINATION.—The proposal  
22          of the Network Administrator for a recal-  
23          culated fee under clause (i) shall take ef-  
24          fect unless the Secretary, within 60 days of  
25          receiving the proposal, provides the Net-



work Administrator with a written determination, with justification, that the proposed fee level does not meet the requirement of subparagraph (A).

“(4) USE OF FEES.—

“(A) IN GENERAL.—All fees collected by the Network Administrator under this subsection shall be available to the Network, without fiscal year limitation, for use in carrying out the functions described in subsection (f).

“(B) RESTRICTION.—Fees collected under this subsection may not be used for any activity for which contract funds may not be used under this section.

“(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as prohibiting the Network Administrator from collecting or accepting other fees, donations or gifts or for using such other fees, donations or gifts to carry out activities other than those authorized under the contract under this section.

“(j) OVERSIGHT OF NETWORK PARTICIPANTS.—

“(1) MONITORING.—

“(A) IN GENERAL.—The OPTN Board and the Network Administrator shall, on an on-

1           going and periodic basis, or as requested by the  
2           Secretary, monitor the operations of Network  
3           participants to determine whether the partici-  
4           pants are maintaining compliance with the cri-  
5           teria and policies established by the OPTN  
6           Board.

7           “(B) PROCEDURES.—

8                   “(i) NOTICE.—In monitoring a Net-  
9           work participant under subparagraph (A),  
10          the OPTN Board or the Administrator—

11                   “(I) shall inform the participant  
12           and the Secretary upon initiating a  
13           compliance review of a Network par-  
14           ticipant; and

15                   “(II) shall inform the participant  
16           and the Secretary of any findings in-  
17           dicating noncompliance by the partici-  
18           pant with such criteria and policies.

19                   “(ii) APPEALS.—The Network Admin-  
20           istrator shall establish procedures for ap-  
21           pealing noncompliance determinations.  
22           Such procedures shall ensure due process  
23           and shall allow for corrective action.

24          “(2) PEER REVIEW PROCEEDINGS.—

1           “(A) IN GENERAL.—The OPTN Board  
2 shall establish a peer review system and condi-  
3 tions for the application of peer review require-  
4 ments to ensure that members of the Network  
5 comply with policies and criteria established by  
6 the OPTN Board under this section. Such peer  
7 review system may include prospective reviews  
8 and shall be administered by the Network Ad-  
9 ministrator and overseen by the OPTN Board.

10           “(B) POLICIES, REVIEW AND EVALUA-  
11 TION.—As part of the peer review system estab-  
12 lished under subparagraph (A), the OPTN  
13 Board shall establish such policies, and the Net-  
14 work Administrator shall conduct such ongoing  
15 and periodic reviews and evaluations of mem-  
16 bers of the Network, as necessary to ensure  
17 compliance with the policies and criteria estab-  
18 lished by the OPTN Board under this section.

19           “(C) EMERGING ISSUES.—As part of such  
20 peer review system established under subpara-  
21 graph (A), the OPTN Board shall establish  
22 policies to work with and direct the Network  
23 Administrator to respond to emerging issues  
24 and problems.

25           “(k) ENFORCEMENT.—

1           “(1) RECOMMENDATIONS.—The OPTN Board  
2           or the Network Administrator shall provide advice,  
3           and make recommendations for appropriate action,  
4           to the Secretary concerning the results of any re-  
5           views or evaluations that, in the opinion of the  
6           OPTN Board or the Network Administrator,  
7           indicate—

8                   “(A) noncompliance by Network partici-  
9           pants with—

10                   “(i) the policies or criteria established  
11                   by the OPTN Board; or

12                   “(ii) the operating procedures of the  
13                   Network Administrator; or

14                   “(B) a risk to the health of organ trans-  
15           plant patients or to public safety.

16           “(2) ENFORCEMENT BY NETWORK.—

17                   “(A) IN GENERAL.—If the OPTN Board  
18           determines that one of the members of the net-  
19           work has violated a requirement established by  
20           this section or by the Network, the OPTN  
21           Board may impose on the member 1 or more of  
22           the sanctions described in subparagraph (B), or  
23           may recommend that the Secretary take en-  
24           forcement action under paragraph (3).



1           “(B) TYPES OF SANCTIONS.—The sanc-  
2           tions described in this subparagraph may  
3           include—

4                   “(i) the loss of any or all privileges of  
5                   membership in good standing in the Net-  
6                   work;

7                   “(ii) the imposition upon the member  
8                   of additional or more frequent reviews or  
9                   evaluations under subsection (j)(1)(A), and  
10                  assessments of the reasonable costs of such  
11                  additional or more frequent reviews or  
12                  evaluations; and

13                  “(iii) such other sanctions as the Sec-  
14                  retary may permit the OPTN Board to im-  
15                  pose.

16           “(3) ENFORCEMENT BY THE SECRETARY.—

17                   “(A) IN GENERAL.—If the Secretary, after  
18                   consultation with the OPTN Board or Network  
19                   Administrator, determines that a member of the  
20                   Network has violated a requirement established  
21                   by this section or a requirement of a policy that  
22                   is enforceable under subsection (f), the Sec-  
23                   retary may impose on the member 1 or more of  
24                   the sanctions described in subparagraph (B).

1           “(B) TYPES OF SANCTIONS.—The sanc-  
2           tions described in this subparagraph shall  
3           include—

4                   “(i) requiring the member to follow a  
5                   directed plan of correction;

6                   “(ii) imposing upon the member a  
7                   monetary assessment (to be paid to the  
8                   General Fund of the Treasury) in an  
9                   amount not to exceed \$10,000 for each  
10                  violation or for each day of violation;

11                  “(iii) requiring the member to pay to  
12                  the Network Administrator the costs of on-  
13                  site monitoring of the member;

14                  “(iv) the loss of any or all privileges  
15                  of membership in the Network; and

16                  “(v) in cases where the violation cre-  
17                  ates a risk to patient health or to public  
18                  health, such other action as the Secretary  
19                  determines to be necessary.

20           “(C) PROCEDURES.—The Secretary shall  
21           develop and implement procedures for the im-  
22           position of sanctions under clauses (i) through (v)  
23           of subparagraph (B). Such procedures shall  
24           include—

“(i) the provision of reasonable notice to the Network member and the OPTN Board that the Secretary is considering imposing a sanction;

“(ii) affording the member a reasonable opportunity to be heard in response to the notice;

“(iii) the provision of notice to the member that the Secretary has decided to impose a sanction; and

“(iv) the opportunity for the Network member to appeal such sanction.

“(1) ANNUAL REPORT.—

“(1) IN GENERAL.—Not later than September 30 of each year, the Network Administrator shall prepare and submit to the Secretary an annual report on the performance and policies of the Network. The report shall include additional items as specified in the contract under this section or requested in a timely manner by the Secretary.

“(2) REQUIREMENT OF OPTN BOARD APPROVAL.—The OPTN Board shall review and approve the report required under paragraph (1) prior to the submission of such report to the Secretary.

“(3) SUBMISSION TO CONGRESS.—

1           “(A) IN GENERAL.—Not later than De-  
 2           cember 31 of each year, the Secretary shall  
 3           transmit the report submitted under paragraph  
 4           (1) and the comments of the Secretary con-  
 5           cerning such report, to the appropriate commit-  
 6           tees of Congress.

7           “(B) CLARIFYING INFORMATION.—The  
 8           Secretary may, upon the receipt of the report  
 9           under paragraph (1), but prior to transmission  
 10          of the report to Congress under subparagraph  
 11          (A), request that the Network Administrator  
 12          submit clarifying information or an addenda as  
 13          needed to fulfill the requirements of this sub-  
 14          section.

15          “(m) AUTHORIZATION OF APPROPRIATIONS.—There  
 16          is authorized to be appropriated to carry out this section,  
 17          such sums as may be necessary for each of fiscal years  
 18          2001 through 2005.”.

### 19   **SEC. 3. SCIENTIFIC REGISTRY**

20          Section 373 of the Public Health Service Act (42  
 21          U.S.C. 274a) is amended to read as follows:

#### 22   **“SEC. 373. SCIENTIFIC REGISTRY.**

23          “The Secretary shall by contract, develop and main-  
 24          tain a scientific registry of the recipients of organ trans-  
 25          plants. The registry shall include information, with respect



1 to organ transplant patients and transplant procedures,  
2 as the Secretary determines to be necessary to an ongoing  
3 evaluation of the scientific and clinical status of organ  
4 transplantation.”.

5 **SEC. 4. ORGAN DONATION.**

6 Part H of title III of the Public Health Service Act  
7 (42 U.S.C. 273 et seq.) is amended—

8 (1) by redesignating section 378 (42 U.S.C.  
9 274g) as section 379; and

10 (2) by inserting after section 377 (42 U.S.C.  
11 274f) the following:

12 **“SEC. 378. ORGAN DONATION AND RESEARCH.**

13 **“(a) INTER-AGENCY TASK FORCE ON ORGAN DONA-**  
14 **TION AND RESEARCH.—**

15 **“(1) IN GENERAL.—**The Secretary shall estab-  
16 lish an inter-agency task force on organ donation  
17 and research (referred to in this section as the ‘task  
18 force’) to improve the coordination and evaluation  
19 of—

20 **“(A)** federally supported or conducted  
21 organ donation efforts and policies; and

22 **“(B)** federally supported or conducted  
23 basic, clinical and health services research (in-  
24 cluding research on preservation techniques and  
25 organ rejection and compatibility).

1           “(2) COMPOSITION.—The task force shall be  
2       composed of—

3           “(A) the Surgeon General, who shall serve  
4       as the chairperson;

5           “(B) representatives to be appointed by  
6       the Secretary from relevant agencies within the  
7       Department of Health and Human Services (in-  
8       cluding the Health Resources and Services Ad-  
9       ministration, Health Care Financing Adminis-  
10      tration, National Institutes of Health, and  
11      Agency for Healthcare Research and Quality);

12          “(C) a representative from the Department  
13      of Transportation;

14          “(D) a representative from the Depart-  
15      ment of Defense;

16          “(E) a representative from the Department  
17      of Veterans Affairs;

18          “(F) a representative from the Office of  
19      Personnel Management; and

20          “(G) representatives of other Federal  
21      agencies or departments as determined to be  
22      appropriate by the Secretary.

23          “(3) ANNUAL REPORT.—In addition to activi-  
24      ties carried out under paragraph (1), the task force

1 shall support the development of the annual report  
2 under subsection (d)(2).

3 “(4) TERMINATION.—The task force may be  
4 terminated at the discretion of the Secretary fol-  
5 lowing the completion of at least 2 annual reports  
6 under subsection (d). Upon such termination, the  
7 Secretary shall provide for the on-going coordination  
8 of federally supported or conducted organ donation  
9 and research activities.

10 “(b) EDUCATION.—

11 “(1) PUBLIC EDUCATION AND AWARENESS.—  
12 The Secretary shall, directly or through grants or  
13 contracts, carry out a comprehensive and effective  
14 national public education program to increase organ  
15 donation, including living donation.

16 “(2) DEVELOPMENT OF CURRICULA AND  
17 OTHER EDUCATION ACTIVITIES.—

18 “(A) IN GENERAL.—The Secretary shall  
19 support the development and dissemination of  
20 model curricula to train health care profes-  
21 sionals and other appropriate professionals (in-  
22 cluding religious leaders in the community and  
23 law enforcement officials) in issues surrounding  
24 organ donation, including methods to approach

1 patients and their families, cultural sensitivities,  
2 and other relevant issues.

3 “(B) HEALTH CARE PROFESSIONALS.—

4 For purposes of subparagraph (A), the term  
5 ‘health care professionals’ includes—

6 “(i) medical students, residents and  
7 fellows, attending physicians (through con-  
8 tinuing medical education courses and  
9 other methods), nurses, social workers, and  
10 other allied health professionals; and

11 “(ii) hospital- or other health care-fa-  
12 cility based chaplains; and

13 “(iii) emergency medical personnel.

14 “(c) GRANTS.—The Secretary shall award peer-re-  
15 viewed grants to public and non-profit private entities, in-  
16 cluding States, to carry out studies and demonstration  
17 projects to increase organ donation rates, including living  
18 donation. The Secretary shall ensure that activities carried  
19 out by grantees under this subsection are evaluated for  
20 effectiveness and that such findings are disseminated.

21 “(d) REPORTS.—

22 “(1) IOM REPORT ON BEST PRACTICES.—

23 “(A) IN GENERAL.—The Secretary shall  
24 enter into a contract with the Institute of Medi-  
25 cine to conduct an evaluation of the organ do-



1 nation practices of organ procurement organiza-  
2 tions, States, other countries, and other appro-  
3 priate organizations that have achieved a higher  
4 than average organ donation rate.

5 “(B) BARRIERS.—In conducting the eval-  
6 uation under subparagraph (A), the Institute of  
7 Medicine shall examine existing barriers to  
8 organ donation.

9 “(C) REPORT.—Not later than 18 months  
10 after the date of enactment of this section, the  
11 Institute of Medicine shall submit to the Sec-  
12 retary a report concerning the evaluation con-  
13 ducted under this paragraph. Such report shall  
14 include recommendations for administrative ac-  
15 tions and, if necessary, legislation in order to  
16 replicate the best practices identified in the  
17 evaluation and to otherwise increase organ do-  
18 nation and procurement rates.

19 “(2) ANNUAL REPORT ON DONATION.—

20 “(A) IN GENERAL.—Not later than 1 year  
21 after the date on which the report is submitted  
22 under paragraph (1)(C), and annually there-  
23 after, the Secretary shall prepare and submit to  
24 Congress a report concerning federally sup-  
25 ported or conducted organ donation and pro-

1       curement activities, including donation and pro-  
2       curement activities evaluated or conducted  
3       under subsection (a) to increase organ dona-  
4       tion.

5               “(B) REQUIREMENTS.—To the extent  
6       practicable, each annual report under subpara-  
7       graph (A) shall—

8               “(i) evaluate the effectiveness of ac-  
9       tivities, identify best practices, and make  
10      recommendations regarding broader adop-  
11      tion of best practices with respect to organ  
12      donation and procurement;

13              “(ii) assess organ donation and pro-  
14      curement activities that are recently com-  
15      pleted, current or planned.

16      “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
17      is authorized to be appropriated to carry out this section,  
18      \$15,000,000 for fiscal year 2001, and such sums as may  
19      be necessary for each of fiscal years 2002 through 2005.”.

CMS Library  
C2-07-13  
7500 Security Blvd.  
Baltimore, Maryland 21244

CMS LIBRARY



3 8095 00010353 7